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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,129	BAGCHI ET AL.	
	Examiner	Art Unit	
	GREGG POLANSKY	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9-11,18,25,32,36-43,51-53,60,67,74,78-85 and 93-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-11,18,25,32,36-43,51-53,60,67,74,78-85 and 93-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 1/15/2008 has been entered.

2. Applicants' submission, filed 1/15/2008, amends Claims 1, 32, 42, 43, 74 and 84, and adds Claims 105 and 106. Claims 2-8, 12-17, 19-24, 26-31, 33-35, 44-50, 54-59, 61-66, 68-73, 75-77 and 86-92 were previously or are newly canceled.

3. Claims 1, 9-11, 18, 25, 32, 36-43, 51-53, 60, 67, 74, 78-85 and 93-106 are pending and are presently under consideration.

4. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Objection

5. Claim 103 is objected to for the following informality: The claim recites "[a] composition of claim 98, wherein, if the composition comprises **g acid**…" (emphasis added). It appears that this is a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 85 and 93-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 95-97 recite the limitation "[a] composition of claim 85, wherein the amount of hydroxycitric acid sufficient to decrease the ghrelin levels is approximately" 900-4500 mg, 2000-3500 mg, or 2700-2800 mg, respectively. Claim 85 is drawn to a composition of hydroxycitric acid, not a method of decreasing ghrelin levels. Therefore, there is insufficient antecedent basis for the recited dose limitations in the claim.

Claim 85 recites, "wherein the hydroxycitric acid is bound to calcium and potassium." On page 3, paragraphs [00011] and [00012] of the Specification, support is provided for the binding of hydroxycitric acid to one or more metals to form a single, double or triple salt wherein the metals are Li, Na, K, Cs, Fr, Be, Mg, Ca, Sr, Ba or Ra. Claim 85 can be interpreted as being drawn to a mixture of calcium hydroxycitric acid and potassium hydroxycitric acid, not a dual salt. It is unclear whether Applicants contemplate a mixture of calcium hydroxycitric acid and potassium hydroxycitric acid or a dual salt. Clarification is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 9-11,18, 24, 43, 51-53, 58-60, 66, 67, 72, 73, 85 and 93-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhaskaran et al., (U.S. 2003/0207942).

Bhaskaran teaches compositions comprising combined potassium-calcium salts of hydroxycitric acid in amounts ranging from about 15 mg to about 3 gm administered up to three times per day. See Example 3, page 4, and page 6, paragraph [0058]. The reference also teaches hydroxycitric acid is derived from the rind of the fruits of *Garcinia cambogia.* See Abstract.

Decreasing ghrelin levels is an inherent property of hydroxycitric acid. See *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) that discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205

USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

It is noted that Claims 85 and 93-97 are drawn to a composition of hydroxycitric acid. The intended use of the compositions confers no patentable weight to the claims. *In re Hack*, 114 USPQ 161.

10. Claims 1, 9, 10, 43, 51, 52, 85, 93, 94, 105 and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by Balasubramanyam et al. (U.S. Patent No. 6,160,172).

Balasubramanyam et al. teach double metal salts of group IA and IIA of hydroxycitric acid which are useful in beverage and various food product formulations without affecting their flavor and properties. The group IA metals include potassium and the group IIA metals include calcium (as required by instant Claims 105-106). See column 1, 1st paragraph and column 2, lines 23-27. The reference teaches hydroxycitric acid is derived from the rind of the fruits of *Garcinia* species, as, for example, *Garcinia cambogia*. See column 1, 2nd paragraph. Balasubramanyam et al. also teach hydroxycitric acid useful in weight reduction. See column 1, 3rd paragraph.

As presented *supra*, decreasing ghrelin levels is an inherent property of hydroxycitric acid.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 9-11, 18, 25, 32, 36-43, 51-53, 60, 67, 74, 78-85 and 93-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raju, G. (WO 99/03464), in view of Policapelli et al. (U.S. Patent No. 5,612,039), Allen, A. (U.S. Patent No. 5,480,657), Alviar et al. (U.S. Patent No. 6,413,545), and Balasubramanyam et al. (U.S. Patent No. 6,160,172).

Raju teaches hydroxycitric acid compositions that comprise both calcium and potassium for use in the reduction of body weight. See the Abstract. The source of the hydroxycitric acid is found in the rind of the fruits of *Garcinia* species, as, for example, *Garcinia cambogia*. See page 1, lines 21-23, as well as page 3, lines 21-24. As required by instant claims 11, 18, 25, 53, 60, 67, 95-97, a suitable dosage ranges from about 15 to about 3000 mg of hydroxycitric acid up to three times per day (15 to 9000 mg hydroxycitric acid per day). See page 10, lines 18-24.

Policappelli teaches the administration of dietary compositions for weight loss comprising *Garcinia cambogia* in addition to *Gymnema sylvestre* extract and chromium bound to nicotinate. See claim 8, column 10, where, as required by instant claims 32 and 74, the administration of the composition is three times daily before a meal.

Allen teaches compositions for treatment of weight gain comprising caffeine, as for example, in tea, in addition niacin-bound chromium. See the Abstract. As required by instant claims 83, 84, 103 and 104, the chromium is present in an amount of approximately 5 mcg to 500 mcg. See lines 1-2, column 9.

Alviar teaches compositions for managing body weight comprising effective amounts of *Garcinia cambogia* extract and *Gymnema sylvestre* extract. As required by instant claims 41, 42, 83, 84, 103 and 104, the daily effective amount of Gymnema *sylvestre* extract is from about 27 to about 293 mg. See column 3, lines 58-62. The open language of the present claims allows for the inclusion of any number of additional active agents.

The teachings of Balasubramanyam et al. are presented *supra*.

Decreasing ghrelin levels is deemed to be an inherent property. See MPEP 2112(1) "[T}he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed.Cir. 1999). Thus, claiming a new use, new function or unknown property which is, absent factual evidence to the contrary, present in the prior art does not necessarily make the claim patentable. *In re Best,* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

With respect to claimed dosage ranges of the active agents in the instant compositions and methods of use, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(11). The determination of the optimum dosage regimen to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific dosage amounts and dosage regimens are not

seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

In view of the combined references set forth *supra*, one skilled in the art would have been motivated to prepare a composition comprising hydroxycitric acid, optionally bound to calcium and potassium or as a dual salt of calcium and potassium, that is derived from the plant *Garcinia cambogia*, optionally further comprising gymnemic acid, tea, niacin-bound chromium and caffeine in methods to reduce body weight. Such would have been obvious in the absence of evidence to the contrary because each of the claimed components in Applicants' compositions is disclosed in the prior art for the purpose of reducing body weight.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. In the last Office Action claims 85-104 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-41 of copending Application No. 09/463024. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending application is drawn to compositions comprising a salt of hydroxycitric acid wherein the claimed concentration ranges are encompassed in the present claim language. The open language of the claims allows for the inclusion of additional active agents in the compositions.

16. Applicants elect to hold this issue in abeyance. The rejection of Claims 85 and 94-103 on the ground of nonstatutory obviousness-type double patenting is maintained, and presently extended to include new Claims 105 and 106 for the reasons of record.

Response to Arguments

17. Applicants' arguments filed 1/15/2008 have been fully considered but they are not persuasive.

Applicants urge the rejection for indefiniteness under 35 U.S.C. § 112, 2nd paragraph, should be withdrawn in light of the amendment of claims 8 and 50 to recite that the preferred composition comprises a dual salt of hydroxycitric acid with calcium and potassium. It is noted that Claims 8 and 50 are deleted by Applicants, rendering the rejection to these two claims, moot. However, the rejection was to Claims 8, 50 and

85. Claim 85 is still pending and has not been amended. Therefore, the rejection has been maintained for this claim.

Applicants argue the rejection under 35 U.S.C. 103(a) should be withdrawn because whereas the instant claims are directed to methods for decreasing ghrelin levels in subjects in need thereof, there is no teaching in the art that administration of hydroxycitric acid would reduce ghrelin levels. However, Applicants are directed to the discussion *supra* concerning how hydroxycitric acid reducing ghrelin levels is a property, or inherent feature, of the compound, which does not render it patently distinct over prior art teachings of its formulation or use in the treatment of obesity. Further, it is noted that instant Claims 85 and 93-104 are directed to compositions, not methods. As discussed *supra*, intended use of the compositions confers no patentable weight to the claims.

Applicants' arguments in regard to the Briggs reference are moot since the reference is no longer relied upon in the rejection.

Applicants urge the rejection over Bhaskaran under 35 U.S.C. 102(e) should be withdrawn because Applicants assert "most overweight subjects have low ghrelin levels (and would not appear to be in any need of reducing their ghrelin levels)" and "many subjects with high ghrelin levels are not overweight". Applicants provide references allegedly in support of these statements (Exhibit A: "Ghrelin", http://arbl.cvmbs.colostate.edu/hboods/pathphys/endocrin/gi/ghrelin.html, and Exhibit B: Marchesini et al., J. Clinical Endocrinology and Metabolism, vol. 88, No. 12, 5674-5679 (2003)). However, upon consideration of these references, the Examiner notes that

Exhibit A teaches ghrelin "is a prominent target for development of anti-obesity treatments" (see page 2, 1st paragraph), and Exhibit B teaches ghrelin leads to increased body weight. It has been studied as a possible cause of obesity (see page 2, "Introduction", 1st two sentences).

Instant Claim 1 is drawn to a method for decreasing ghrelin levels in a subject in need thereof. Since there is no disclosure in the claims as to how one of ordinary skill in the art would determine whether said subject were in need of reduced ghrelin levels, one must go to the instant Specification for such guidance. The Specification discloses that increased ghrelin levels increase food intake in rodents and humans and that ghrelin levels rise sharply shortly before and fall shortly after every meal in obese subjects. The Specification further discloses the present invention provides a method and composition (i.e., hydroxycitric acid) that reduces ghrelin levels to decrease and regulate food intake, increase fat metabolism and provide other additional benefits associated with maintaining healthy body weight. See page 1, paragraphs 3 and 4 and page 2, paragraphs 6-8. Thus, the Specification teaches that subjects in need of reduction of ghrelin levels are those subjects in need of reducing body weight. The prior art cited in the instant rejections teaches the use of hydroxycitric acid for weight reduction. It is irrelevant that the prior art did not recognize that hydroxycitric acid reduces ghrelin levels. See the discussion *supra* concerning inherent properties.

Applicants disclose in their arguments that "[i]t is therefore unclear whether administration of HCA to the class of overweight subjects generally or overweight

subjects suffering from nonalcoholic fatty liver disease will decrease ghrelin levels". This statement appears to teach away from the instant invention.

Conclusion

18. Claims 1, 9-11, 18, 25, 32, 36-43, 51-53, 60, 67, 74, 78-85 and 93-106 are rejected

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/

Examiner, Art Unit 1611

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614